DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 28, 1998

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 98-14

M. Sue Preston
Authorized Official
Alpha Therapeutic Corporation
5555 Valley Blvd.
Los Angeles, California 90032-3548

WARNING LETTER

Dear Ms. Preston:

During inspections of two Alpha Therapeutic Corporation plasma centers in Seattle, Washington, located at 5700 Martin Luther King Way South (inspected May 13-26, 1998), and at 7726 15th Avenue NW (inspected June 10-16, 1998), our investigators documented violations of Section 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21CFR) Parts 600-800 as follows:

1. Failure to adequately determine the suitability of donors at the time of collection [640.63(c)], in that Source Plasma was collected from at least five donors who were not asked all the donor screening questions, including questions to determine whether the donor is at increased risk for infection with Human Immunodeficiency Virus (HIV).

2. Failure to maintain standard operating procedures (SOPs) that contain all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components [606.100(b)], in that the SOP regarding disposition and labeling of Source Plasma that has been determined to be appropriate for use only in the further manufacture into in-vitro diagnostic reagents does not specify the types of unsuitable products that can be so labeled. This SOP was used to label and distribute products as "SOURCE PLASMA**FOR FURTHER MANUFACTURE ONLY OF IN

> VITRO DIAGNOSTIC REAGENTS FOR WHICH THERE ARE NO ALTERNATIVE SOURCES" that were collected from donors whose suitability determination was inadequately performed as in item number one above, as well as units collected from donors who were deemed to be unsuitable by your firm based on post donation information concerning close contact with individuals found to be either: a) repeatedly reactive for antibody to hepatitis C virus encoded antigen (anti-HCV); or b) a past or present intravenous drug user.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facilities. It is the responsibility of Alpha Therapeutic Corporation to assure that your establishments are in compliance with all requirements of the federal regulations.

We acknowledge receipt of your letters dated June 26, 1998, and July 9, 1998, that responded to the observations from the inspections conducted May 13-26, 1998, and June 10-16, 1998, respectively. The following comments are provided.

For both inspections, the corrective action which addressed the observations by employee retraining and documentation thereof, is acceptable. However, in addressing item number one above, please indicate any effort made to prevent recurrence.

With regard to your June 26, 1998, and July 9, 1998 letters and item number two above, we note that on July 10, 1998, members of your staff participated in a teleconference with members of our office as well as staff from the Center for Biologics Evaluation and Research. During the teleconference, your staff stated that the process of reclassifying Source Plasma for in-vitro diagnostic reagents was being reviewed and the SOP would be revised. In addition, recognizing that the SOP used to label the Source Plasma for in-vitro diagnostic reagents was used throughout your Source Plasma collection facilities, the need to perform an audit of all collection facilities to determine the scope of possible inappropriate releases of product was discussed during the teleconference. As part of your response to this letter, please provide an update to your efforts.

Finally, the response to the May 13-26, 1998 inspection did not indicate the disposition of the units cited on the FDA 483.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure, and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their

recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, c/o Thomas S. Piekarski, Compliance Officer, at the above mailing address.

Sincerely,

Roger L. Lowell
District Director

cc: Roxanne C. Benson
Center Director
Alpha Therapeutic Corporation
5700 Martin Luther King Way South
Seattle, WA 98118

John W. Luther
Center Director
Alpha Therapeutic Corporation
7726 15th Avenue NW
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